

## REMARKS

### Summary of the Invention

The invention features a biologically pure culture of a newly identified single-celled organism, designated Spiky Rotating Cells (SPR). The invention also features methods for diagnosing an SPR infection, an instrument for collecting a secretion containing SPR and for detecting an SPR infection in the secretion, and methods for treating an SPR infection.

### Support for the Amendments

Support for the amendments to claims 1, 5-7, 9, 10, 12, and 14-17 is found on page 9, lines 6-22, page 10, lines 8-11, page 11, line 20, through page 12, line 7, of the specification, and the claims as originally filed. Support for the use of "loop region with an opening" in claims 14 and 15 is found in Fig. 1, on page 9, lines 8-12 of the specification, and is also inherent in the definition of a loop (see, e.g., The American Heritage® Dictionary of the English Language, Fourth Edition, 2000). Support for new claims 35-37 is found on page 6, lines 11-14, page 7, line 6, through page 8, line 10, page 9, lines 3-22, page 10, lines 1-15, page 12, lines 9-12, page 10, lines 1-15, of the specification, and the claims as originally filed. No new matter is added by the amendments.

### Summary of the Office Action

Claims 1, 2, and 5-34 are pending. Claims 1-21, and 32-34 are rejected under 35 U.S.C. § 112, first paragraph, for containing new subject matter. Claims 1, 2, 5-13, 17, and 18 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 1, 2, and 18-21 are

rejected under 35 U.S.C. § 102(b) for anticipation over Abou El Seoud et al. (J. Egypt. Soc. Parasitol. 28:263-270, 1998; hereinafter "Abou El Seoud"). Claims 1-2 are rejected under 35 U.S.C. § 102(b) for anticipation over Monteiro-Leal et al. (Cell Motility and the Cytoskeleton 34:206-214, 1996; hereinafter "Monteiro-Leal"). Claims 5, 6, 10, 12, and 31-32 are rejected under 35 U.S.C. § 102(b) for anticipation over Abou El Seoud. Claim 5 is rejected under 35 U.S.C. § 102(b) for anticipation over Andrews et al. (U.S. Patent No. 5,300,491; hereinafter "Andrews"). Claims 5, 10, and 11 are rejected under 35 U.S.C. § 102(b) for anticipation over Caillouette et al. (U.S. Patent No. 5,827,200; hereinafter "Caillouette '200"). Claims 5, 10, 11, and 33 are rejected under 35 U.S.C. § 102(b) for anticipation over Caillouette et al. (U.S. Patent No. 5,928,165; hereinafter "Caillouette '165"). Claims 5-7 are rejected under 35 U.S.C. § 102(b) for anticipation over Mennen (U.S. Patent No. 4,108,729; hereinafter "Mennen"). Claims 5, 12, and 13 are rejected under 35 U.S.C. § 102(b) for anticipation over Yeh (U.S. Patent No. 5,725,373; hereinafter "Yeh"). Claims 14-16 are rejected under 35 U.S.C. § 102(e) for anticipation over Caillouette '165. Claim 16 is rejected under 35 U.S.C. § 102(b) for anticipation over Caillouette et al. (U.S. Patent No. 5,577,512; hereinafter "Caillouette '512") and Caillouette et al. (U.S. Patent No. 5,425,377; hereinafter "Caillouette '377"). Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation over Birthistle et al. (Genitourin Med. 72:445-452, 1996; hereinafter "Birthistle"), Larson (U.S. Patent No. 6,180,136; hereinafter "Larson"), and Gray (U.S. Patent No. 5,474,997; hereinafter "Gray"). Claims 5-8, 10-11, and 33 are rejected under 35 U.S.C. § 103(a) for obviousness over Caillouette '165 in view of Kalb et al. (U.S. Patent No. 5,704,353; hereinafter "Kalb"). Claim 9 and 34 are rejected under 35 U.S.C. § 103(a) for obviousness over Caillouette '165 in view of Kalb and Sheiness et al. (U.S. Patent No.

5,776,694; hereinafter "Sheiness"). Claims 22-31 are subject to restriction for reciting a method that is independent and distinct from a method of diagnosing SPR infection.

By this reply, Applicant cancels claims 2, 8, 11, 13, 18, and 22-34, amends claims 1, 5-7, 9, 10, 12, and 14-17, adds new claims 35-37, and addresses each of the Examiner's rejections.

#### Informalities

The Office objects to the phrase "(Rule 28(4)EPC)" on page 13, line 6, of the specification. Applicant has amended the specification to remove the phrase to which the Examiner objected. Accordingly, the objection may be withdrawn.

#### Election/Restriction

The Office withdraws claims 22-31 which are "directed to an invention that is independent or distinct from the invention originally claimed." Applicants respectfully disagree. However, in the interest of moving the presently pending claims towards allowance, Applicant has cancelled claims 22-31 without traverse.

#### Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-21 and 32-34 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner states that the claims "recite the claim limitation 'forming periodic colonies of 2 to 10,000 cells' or in the case of claim 18 'colonies are 2 to 1000 cells.' No original descriptive support for these limitations could be found." Furthermore, the Examiner states that "[t]he specification does not define the SPR as a protozoan, but is

provisionally classified as a protozoan. This newly added phrase to claims 1-2 and 18-21, does not evidence original descriptive support in the specification.” Applicant has amended the claims to recite “provisional classification as a protozoan” in reference to the organism, which the Examiner states does evidence original descriptive support. Accordingly, the rejection of claim 1-21 and 32-34 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-2, 5-13, 17, and 18 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner states that claim 1, which recites an organism having a diameter of 7-8  $\mu\text{m}$ , requires “[c]larification of the recited diameter measurement relative to the recited protozoan and colonial morphology.” Applicant has amended claims 1, 9, and 17, which recite an organism having a spherical shape that measures approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism. Based on this clarification, Applicant respectfully requests that the rejection of claims 1-2, 5-13, 17, and 18 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner also rejects claim 2 under 35 U.S.C. § 112, second paragraph. The Examiner questions “[h]ow claim 2 is further limiting of claim 1?” To address this rejection, Applicant has cancelled claim 2. In addition, Applicant has added new claim 35, which recites a single-celled organism having accession number ATCC PTA-2129. Accordingly, the rejection of claim 2 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Examiner rejects claims 5-13 under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner states that “[t]he testing of the sample is not clear, in light of the claim having been amended and the type of testing [is] not defined to be a test that detects the

structural spiky characteristic and the functional rotating characteristic of the infection causing organism.” Applicant has cancelled claims 8, 11, and 13, and has amended claims 5-7, 9, 10, and 12. Specifically, claim 5, from which claims 6, 7, 9, 10, and 12 depend, now recites testing the sample for the presence of an organism that causes a disease in a human and has the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment. The identification of an organism having these recited characteristics in a sample obtained from the patient indicates that the patient has an SPR infection. Accordingly, claim 5 now recites morphological characteristics of the SPR organism that one skilled in the art can use to diagnose an SPR infection. Claim 6 adds the further step of testing the pH of the sample wherein a pH of greater than 6.0 is further indicative of the presence of an SPR infection. The specification states that the pH of a genital tract secretion from a human subject that is infected with SPR is higher (i.e., greater than about 6.0 and as high as 7.5) than the normal range (i.e., 4.5-5.0; see page 9, lines 18-22, of the specification). Thus one skilled in the art, using the guidance provided in the specification, could easily follow the method of claim 5 or 6 to diagnose an SPR infection. Applicant has also amended claim 9 to recite that the method of claim 5 additionally involves admixing the sample with saline and examining the sample by microscopy for the identification of an organism with the biological characteristics recited in claim 5. Applicant submits that the amendments to claims 5, 6, and 9, which recite the diagnosis of an SPR infection by detection of identifying morphological characteristics of, or biological characteristics associated with, the SPR organism,

clearly establish the criteria necessary to identify the organism. Therefore, the rejection of claims 5-13 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Examiner rejects claim 17, stating that “the specific ‘SPR’ infection has not been defined to be any specific spiky rotating cells, wherein the definition provided for ‘SPR’ includes both protozoa and bacteria...[and that] Applicant’s arguments are not commensurate in scope with the instantly claimed invention.” In response to this rejection, Applicant has amended claim 17 to recite particular biological characteristics of the SPR organism, thereby clearly identifying the infection to be treated. In light of the present amendment to claim 17, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner also rejects claim 18 under 35 U.S.C. § 112, second paragraph, by stating that the claim is not further limiting of claim 1. Applicant has cancelled claim 18, therefore, this rejection should be withdrawn.

In light of the foregoing remarks, Applicant respectfully requests that the rejection of claims 1-2, 5-13, 17, and 18, under 35 U.S.C. § 112, second paragraph, be withdrawn.

#### Rejections Under 35 U.S.C. § 102(b)

Claims 1-2 are rejected under 35 U.S.C. § 102(b) for anticipation by Abou El Seoud. The Examiner states that “the biologically pure culture of Abou El Seoud anticipates the claimed culture [because]...[n]o specific species of protozoan is claimed and claim 2 is not limited to the ATCC deposit but includes strains that have the characteristics of the deposited strain...” Applicant respectfully traverses this rejection.

The Examiner states that the abstract of Abou El Seoud discloses the formation of colonies by *Trichomonas vaginalis* when grown on Diamond's medium. This is incorrect. Abou El Seoud states that "Diamond's culture proved to be the method of choice....[for] the detection of *T. vaginalis*..." (See abstract, last sentence, and page 268.) Abou El Seoud simply indicates that *T. vaginalis* grows well in Diamond's culture and for this reason, it should be used as "the gold standard for the diagnosis of *T. vaginalis*."

Abou El Seoud does not describe any organism that exhibits periodic colonial clustering. This characteristic does not simply refer to the ability of the presently claimed organism to grow and multiply, but rather, the term indicates that the organism can live at different points in its life cycle as either a single solitary organism or as an organism in a large clustering colony (see page 10, lines 8-15, of the specification and Figures 3 and 4). Abou El Seoud simply fails to disclose this characteristic. Accordingly, Applicant respectfully requests that the rejection of claims 1-2 under 35 U.S.C. § 102(b) be withdrawn.

The Examiner also rejects claims 1-2 under 35 U.S.C. § 102(b) for anticipation by Monteiro-Leal. As is discussed above, claim 1 recites an organism that exhibits periodic colonial clustering. Monteiro-Leal, like Abou El Seoud, fails to describe this characteristic. The Examiner asserts that Monteiro-Leal, which describes the cultivation of *Trichomonas foetus* on TYM medium, discloses the periodic colonial clustering characteristic of the presently claimed organism. Again, this is incorrect. Monteiro-Leal describes the cultivation of *T. foetus*, which is not an organism that can live as both a single solitary organism and an organism in a clustering colony. In light of these remarks, Applicant respectfully requests that the rejection of claims 1-2 under 35 U.S.C. § 102(b) be withdrawn.

Claims 5-6, 10, 12, 31 and 32 are rejected under 35 U.S.C. § 102(b) over Abou El Seoud. The Examiner states that “Abou El Seoud disclose[s]...[a] biologically pure culture of a protozoan single celled organism (*Trichomonas vaginalis*) [therefore,]...Abou El Seoud anticipates the claimed method of diagnosis, as Abou El Seoud diagnoses protozoan infection caused by an organism with the recited characteristics.” Applicant respectfully disagrees.

Claims 31 and 32 have been cancelled and claim 5, from which claims 6, 10, and 12 depend, has been amended to recite a method of diagnosing an SPR infection in a human patient by obtaining a sample from the patient and testing the sample for the presence of an organism that causes a disease in humans and has the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment. Contrary to the Examiner’s statement, Abou El Seoud fails to disclose a diagnosis method which includes identifying an organism with the recited biological and morphological characteristics. Specifically, Abou El Seoud fails to identify any organism that exhibits periodic colonial clustering, let alone provide a method that correlates the presence of such an organism (in a sample from a patient) with an SPR infection. Absent this teaching, Abou El Seoud fails to anticipate the claimed method. For this reason, Applicant respectfully requests that the rejection of claims 5-6, 10, and 12 under 35 U.S.C. § 102(b) over Abou El Seoud be withdrawn.

Claim 5 is rejected under 35 U.S.C. § 102(b) over Andrews. The Examiner states that

Andrews...disclose[s] a method of diagnosing infection in a human patient...[by] obtaining a sample from a patient...and testing for the presence of a single celled organism that is spiky and rotating...[therefore,] Andrews...anticipates the now claimed



method of diagnosing infection in a human patient that has "SPR."

Applicant respectfully disagrees.

Andrews also fails to disclose a method for diagnosing an SPR infection, because Andrews fails to disclose testing for the presence of an organism that exhibits all of the biological and morphological characteristics recited in claim 5 (e.g., periodic colonial clustering). Therefore, Andrews, like Abou El Seoud, fails to anticipate the claimed method because all of the elements of the presently claimed diagnosis method are not taught. Accordingly, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 102(b) over Andrews be withdrawn.

Claims 5 and 10-11 are rejected under 35 U.S.C. § 102(b) over Caillouette '200. The Examiner states that

Caillouette disclose[s] a method of detecting a species of SPR infection in a female patient...[which includes] pathogenic bacteria...that move by Brownian motion and have cilia or flagella...Caillouette...anticipates the claimed invention that is not so limited to [the diagnosis of]...any specific type of "SPR" infection. [Caillouette discloses] obtaining a sample from a patient using an instrument for the collection of a vaginal sample, wherein the instrument comprises a pH sensor that comes in contact with the sample...and testing...the sample for a change in pH to aid in the diagnosis of infection.

Applicant respectfully disagrees.

Claim 5, as presently amended, recites obtaining a sample from a human patient and testing the sample for the presence of an organism that causes a disease in humans and has the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic

colonial clustering; and (vii) exists in an extracellular environment. Claim 10 recites that the sample is a cervico vaginal secretion obtained from the vagina of a female patient. Claim 11 has been cancelled. Caillouette '200 merely describes the detection of pathogenic bacteria in the vagina using an apparatus that enables production of a gaseous odor upon reaction with a vaginal sample (see, e.g., the Abstract, and column 1, lines 7-42). Caillouette '200 fails, however, to describe a method of diagnosing an SPR infection by identifying the organism's morphological characteristics, as is recited in present claim 5. Therefore, Caillouette '200 fails to teach all of the required elements of claim 5, and claims dependent therefrom. Accordingly, Applicant respectfully requests that the rejection of claims 5 and 10-11 under 35 U.S.C. § 102(b) over Caillouette '200 be withdrawn.

Claims 5, 10, 11, and 33 are rejected under 35 U.S.C. § 102(e) over Caillouette '165. The Examiner asserts that Caillouette '165 anticipates the claimed method of diagnosing an SPR infection. Claim 33 has been cancelled and, as is discussed above, Applicant has amended claim 5, from which claims 10 and 11 depend. Claim 5 now requires testing the sample for the presence of an organism with the recited biological characteristics. Caillouette '165, like Caillouette '200, fails to disclose any morphological characteristics with which to identify an SPR organism in a sample from a patient. Accordingly, Caillouette '165 fails to teach all of the recited elements of claim 5, and claims dependent therefrom. Applicant, therefore, respectfully requests that the rejection of claims 5, 10, 11, and 33 under 35 U.S.C. § 102(e) over Caillouette '165 be withdrawn.

Claims 5-7 are rejected under 35 U.S.C. § 102(b) over Mennen. The Examiner states that Mennen anticipates the claimed method of diagnosis of an SPR infection because "the sample of

Mennen...is collected from the meatus of the male penis, defining a urethra sample, and the instantly claimed invention does not recite the *direct* collection of the sample from the male urethra.” Claim 5 now recites diagnosing an SPR infection by identifying the presence of an organism with particular morphological characteristics. Mennen fails to disclose any morphological characteristics that can be used to identify an SPR infection. In light of this omission, Applicant respectfully requests that the rejection of claim 5, and claims dependent therefrom, under 35 U.S.C. § 102(b) over Mennen be withdrawn.

Claims 5 and 12-13 are rejected under 35 U.S.C. § 102(b) over Yeh. The Examiner states that

Yeh does disclose an instrument that could diagnose an SPR infection, wherein the instrument comprises a pH indicator positioned to contact the collected secretion, a collection step, and a testing step in a method of diagnosing infection in a human patient...Inherently the reference anticipates the claimed invention.

Applicant respectfully disagrees.

Yeh describes a periodontal probe tip for diagnosing periodontitis and dental decay by detecting bacteria that “produce acid which will wash away tooth mineral and bone mineral.” (See column 1, lines 41-44.) Yeh fails to specifically teach the diagnosis of an SPR infection by obtaining a sample from a patient and detecting the biological and morphological characteristics recited in present claim 5. Yeh merely relies on the detection of “acidity” as the determinant of infection. Accordingly, Yeh fails to disclose all of the elements of present claim 5, and claims dependent therefrom. Therefore, Applicant respectfully requests that the rejection of claims 5 and 12-13 under 35 U.S.C. § 102(b) over Yeh be withdrawn.

Claims 14-16 are also rejected under 35 U.S.C. § 102(e) over Caillouette ‘165. The

Examiner states that because the claims recite the phrase “comprises a loop” instead of the phrase “consists of a loop region,” “Applicant’s arguments are not commensurate in scope with the instantly claimed invention.” Furthermore, the Examiner states that

Caillouette...disclose[s]...an instrument for the collection of a vaginal or urethral sample, wherein the instrument comprises a pH sensor that comes in contact with the sample...The intended use of the claimed instrument...does not define over the applied prior art...The instrument of Caillouette...could be inserted into the distal end of the urethra of a male patient.

Applicant respectfully disagrees.

Applicant has amended claims 14, 15, and 16. Claim 14 now recites that the collecting means for the instrument “is sized and shaped for insertion into the distal end of the urethra of said male patient and comprises a loop region with an opening.” (Emphasis added.) Support for this amendment is found in Fig. 1, on page 9, lines 8-12, of the specification, and is also inherent in the definition of a loop. See, e.g., The American Heritage® Dictionary of the English Language, Fourth Edition, 2000, which defines a loop as “a length of line, thread, ribbon, or other thin material that is curved or doubled over making an opening.” Applicant directs the Examiner to column 4, line 56, through column 5, line 15, of Caillouette ‘165, which indicates that the instrument consists of a “swabbing means [that] comprise[s] a soft cotton swab, or other absorbent material, attached to the carrier stick at its opposite end.” The method of Caillouette ‘165 directs the user to “swab the vaginal cavity or the urethra.” Clearly Caillouette ‘165 fails to disclose an instrument with a collecting means that comprises a loop region with an opening that is sized and shaped for insertion into the distal end of the urethra of a male patient. In fact, Caillouette ‘165 clearly describes an instrument that is used by swabbing the urethra to obtain urethral moisture, but that requires the addition of a “smoothed surfaced protective tip” for

insertion into the male urethra (see column 2, lines 59-64). Therefore, the instrument of Caillouette '165 fails to disclose all of the recited elements of the instrument of present claim 14.

Claim 15, as presently amended, recites, *inter alia*, an instrument that comprises a loop region with an opening. As is discussed above, Caillouette '165 clearly fails to describe an instrument with the recited elements (see, for example, Fig. 1, as well as column 4, line 56, through column 5, line 15, of Caillouette '165). The cotton swab that provides the collecting means for the instrument of Caillouette '165 is clearly solid, or at the very least consists of a mass that lacks a definite opening (this is important for the reasons described below). Therefore, Caillouette '165 fails to teach all of the required elements of the instrument of claim 15.

In addition, Applicant submits that the instrument of Caillouette '165 (i.e., an instrument that contains a cotton swab or other absorbent material as the collecting means) would fail to provide the same benefit as the instrument of present claims 14 and 16. As is discussed above, the SPR organism exhibits changes in its morphology at different stages of the life cycle (i.e., during its life cycle, SPR can exist as either a single-celled organism or clustered in a colonial architecture). The ability to identify SPR in either of its two forms is critical to the diagnosis of an SPR infection. The instrument of Caillouette '165, which utilizes absorbent material as the collecting means, would interfere with the diagnosis of an SPR infection in either of its two stages for the following reasons. First, the SPR organism in either its single-celled stage or its clustering stage would bind to and become entangled in the absorbent material of the Caillouette '165 instrument, making it very difficult to separate the organism from the absorbent material. In contrast, the open loop of the presently claimed instrument does not entangle the SPR organism, therefore, the SPR organism is easily collected by and released from the presently

claimed instrument. Second, the absorbent material of the instrument of Caillouette '165 would disrupt the distinctive colonial clustering architecture of the SPR organism. Because this morphological feature can be used to identify the SPR organism, it is important to collect the organism with minimal disruption. Because the instrument of Caillouette '165 utilizes absorbent material as the collecting means, separation of the SPR organism from the collecting means would be very difficult and may require vigorous shaking. This would likely result in disruption of the colonial clustering architecture. In contrast, the instrument of present claims 14 and 15 utilizes a loop region at the tip of the instrument, which would enable collection and separation of the urethral or vaginal SPR-containing secretion with a minimal amount of disruption. Furthermore, the instrument of present claim 14 can be easily inserted into the distal end of the urethra of a male patient without causing excessive discomfort to the male patient, and without requiring modification. As is discussed above, the instrument of Caillouette '165 requires modification for this purpose.

In light of the above remarks, Applicant respectfully requests that the rejection of claims 14-16 under 35 U.S.C. § 102(e) be withdrawn.

Claim 16 is rejected under 35 U.S.C. § 102(b) over Caillouette '512 or Caillouette '377. Applicant points out that the subject matter of claim 16 is now provided as claim 15. Applicant submits that the instrument described in Caillouette '512 and Caillouette '377 also fails to anticipate the instrument of present claim 15 for the reasons discussed above under the rejection of claims 14-16 over Caillouette '165.

Claim 17 is rejected under 35 U.S.C. § 102(b) over Birthistle, Larson, and Gray. The Examiner states that "while the references do not recite the term 'SPR', the instantly claimed

invention is directed to a genus of methods of ‘treating an SPR infection in a patient’, wherein the infecting agent is an organism that is spiky and rotates.” Applicant respectfully disagrees.

The method of present claim 17 first requires diagnosing the presence of an SPR infection in which the SPR organism causes a disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment. None of Birthistle, Larson, or Gray disclose the diagnosis or treatment of an organism with all of these biological and morphological characteristics. Therefore, these characteristics can be used to clearly distinguish the SPR organism over the prior art organisms described in Birthistle, Larson, and Gray. Accordingly, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 102(b) be withdrawn.

#### Rejections under 35 U.S.C. § 103

Claims 5-8, 10-11, and 33 are rejected under 35 U.S.C. § 103(a) over Caillouette ‘165 in view of Kalb. The Examiner states that Caillouette ‘165 “discloses a method of diagnosing infection that utilizes a collection instrument that contains a pH indicator...and...has the shape of a loop,” but that “fail[s] to teach the instrument...formulated for a male urethra.” Kalb provides a collection instrument for obtaining a male urethral secretion. The Examiner then states that “it would have been obvious to the person of ordinary skill in the art to obtain a male urethra sample with an instrument as taught by Caillouette ‘165 formulated for a male, as suggested by Kalb et

al.” Applicant respectfully disagrees.

Applicant has cancelled claims 8, 11, and 33. The following remarks are directed to pending claims 5, 6, 7, and 10. Claim 5, from which claims 6, 7, and 10 depend, is directed to a method of diagnosing an SPR infection that, as is discussed above, is distinguished from the prior art by the recitation of the particular biological characteristics used to identify an SPR organism. Neither Caillouette ‘165 nor Kalb teach or suggest any of the biological characteristics recited in present claim 5. Caillouette ‘165 merely discloses a device for obtaining a vaginal or urethral moisture sample and detecting the pH of that sample. Caillouette ‘165 fails to disclose any teaching or suggestion that would guide one skilled in the art to make a determination that the sample contained an infecting SPR organism. Kalb also fails to provide this missing element. Kalb describes a urinary catheter for placement in the urethra of a human body. Therefore, neither Caillouette ‘165 nor Kalb, either singly or in combination, teach or suggest all of the limitations of present claim 5, and claims dependent therefrom. Accordingly, Applicant respectfully requests that the rejection of claims 5-8, 10-11, and 33 under 35 U.S.C. § 103(a) be withdrawn.

Claims 9 and 34 are rejected under 35 U.S.C. § 103(a) over Caillouette ‘165 in view of Kalb as applied to claims 5-8, 10-11, and 33, and further in view of Sheiness. The Examiner states that Caillouette ‘165 “teaches the formulation of an instrument that comprises a loop shaped component for obtaining a urethra sample from a patient [that] could be used for the collection of a urethra sample from the distal end of a male patient.” The Examiner adds that “Kalb teaches...[the] formulation of an instrument for obtaining both male and female urethra samples, wherein the instrument tests for various infection associated parameters, [and] to



include pH was known in the art at the time the invention was made.” Finally, the Examiner states that

Sheiness...[teaches] the classical testing of a sample for the presence of spiky rotating pathogens..., wherein the method of diagnosis comprise[s] not only pH testing,...but also...visual evaluation through combining the sample with saline in order [to] assess motility (rotating), size and physical structures (spiky)...

Applicant respectfully disagrees.

Applicant has cancelled claim 34 and has amended claim 9, which depends from claim 5, to recite a method of diagnosing an SPR infection by admixing a sample with saline and examining the sample by microscopy to confirm the presence of an organism that causes disease and has the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment. As is discussed above, neither Caillouette ‘165 nor Kalb teach or suggest the diagnosis of an SPR infection by identifying the presence of an organism with the recited characteristics. Sheiness also fails to disclose the identification of an organism having the particular characteristics described. Furthermore, none of the references cited by the Examiner teaches or suggests the confirmation of an SPR infection by microscopically detecting an organism with the above-recited characteristics. Specifically, none of Caillouette ‘165, Kalb, or Sheiness teaches or suggests the confirmation of an SPR infection by microscopically detecting an organism exhibiting periodic colonial clustering. Because Caillouette ‘165, Kalb, and Sheiness fail to teach or suggest all of the claim limitations, either singly or in combination, Applicant respectfully requests that the

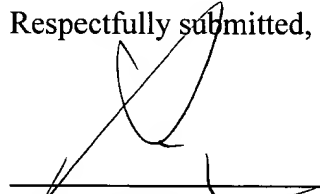
rejection of claims 9 and 34 under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for replying for two months, to and including April 5, 2003. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Version with markings to show changes made

In the Specification:

A marked-up version of the paragraph on page 13, lines 1-6, of the specification is presented below.

In respect of those designations in which a European patent is sought, a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample. [(Rule 28(4) EPC)]

In the Claims:

A marked-up version of claims 1, 5-7, 9, 10, 12, 14, 16, and 17 is presented below.

1. (Twice Amended) A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), wherein said organism causes a disease in humans [is a protozoan] and has: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) [(ii) a protozoan having] spiky membrane projections; (iv) [(iii) a protozoan having] a refractile cell membrane; (v) [(iv) a protozoan exhibiting] rotatory motility; (vi) [(v) a protozoan, said protozoan forming] periodic colonial clustering [colony formation]; and (vii) exists in [(vi) a protozoan, said protozoan living in] an extracellular environment [; and (vii) causes disease in humans].

5. (Twice Amended) A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:

- a) obtaining a sample from said patient; and
- b) testing said sample for the presence of an organism that causes a disease in humans, said organism having the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment; wherein the presence of said organism indicates an SPR infection [SPR, wherein the presence of SPR indicates an SPR infection].

6. (Twice Amended) The method of claim 5, wherein said method further comprises, after step a), testing the pH of said sample, wherein a pH greater than 6.0 is further indicative of the presence of said SPR infection [any of claims 5, 22, 23, or 24, wherein said patient is a male, and wherein step a) comprises collecting said sample from the urethra of said male patient, wherein said sample is a secretion found in the urethra of said male patient].

7. (Twice Amended) The method of claim 5, wherein said patient is a male, and wherein step a) comprises obtaining said sample from the urethra of said male patient, wherein said sample comprises a secretion found in the urethra of said male patient [6, wherein said secretion is collected with an instrument that includes a pH indicator positioned to contact said secretion].

9. (Twice Amended) The method of claim 5 [8], wherein step b) comprises [said testing comprises] admixing said sample with saline and examining said sample by microscopy, wherein said SPR infection is confirmed by the presence of an organism comprising said biological characteristics.

10. (Twice Amended) The method of [any of claims 5, 22, 23, or 24] claim 5, wherein said patient is a female, and wherein step a) comprises obtaining [collecting] a sample from the vagina of said female patient, wherein said sample comprises [is] a cervico vaginal secretion from said female patient.

12. (Twice Amended) The method of [any of claims 5, 22, 23, or 24] claim 5, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises a secretion from said skin eruption or abscess.

14. (Twice Amended) An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

- a) a handle portion; and
- b) attached to said handle portion, a means for collecting secretions from the reproductive system of said male patient, wherein said collecting means is sized and shaped for insertion into the distal end of the urethra of said male patient and comprises a hollow loop region; and
- c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample].

15. (Amended) An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, said instrument comprising:

- a) a handle portion; and
- b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a hollow loop region [The instrument of claim 14, wherein said collecting means is adapted for insertion into the distal end of the urethra of a male patient].

16. (Twice Amended) The instrument of claim 14 or (16), wherein said instrument further comprises a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample [An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, said instrument comprising:

- a) a handle portion;

- b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a loop; and
- c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample].

17. (Twice Amended) A method of treating an SPR infection in a patient, said method comprising:

a) diagnosing said SPR infection, wherein the organism causing said SPR infection causes a disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu$ m as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment, and wherein said organism causes disease in humans; and

b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin, and metronidazole.

### Claims as Pending

1. A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), wherein said organism causes a disease in humans and has the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment.

5. A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:

a) obtaining a sample from said patient; and  
b) testing said sample for the presence of an organism that causes a disease in humans, said organism having the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment; wherein the presence of said organism indicates an SPR infection.

6. The method of claim 5, wherein said method further comprises, after step a), testing the pH of said sample, wherein a pH greater than 6.0 is further indicative of the presence of said SPR infection.

7. The method of claim 5, wherein said patient is a male, and wherein step a) comprises obtaining said sample from the urethra of said male patient, wherein said sample comprises a secretion found in the urethra of said male patient.

9. The method of claim 5, wherein step b) comprises admixing said sample with saline and examining said sample by microscopy, wherein said SPR infection is confirmed by the presence of an organism comprising said biological characteristics.

10. The method of claim 5, wherein said patient is a female, and wherein step a) comprises obtaining a sample from the vagina of said female patient, wherein said sample comprises a cervico vaginal secretion from said female patient.

12. The method of claim 5, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises a secretion from said skin eruption or abscess.

14. An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

a) a handle portion; and  
b) attached to said handle portion, a means for collecting a secretion from the reproductive system of said male patient, wherein said collecting means is sized and shaped for

insertion into the distal end of the urethra of said male patient and comprises a loop region with an opening.

15. An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, and detecting the presence of SPR in said secretions, said instrument comprising:

- a) a handle portion;
- b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a loop region with an opening; and
- c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

16. The instrument of claim 14 or 16, wherein said instrument further comprises a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

17. A method of treating an SPR infection in a patient, said method comprising:

- a) diagnosing said SPR infection, wherein the organism causing said SPR infection causes a disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism; (iii) spiky membrane projections; (iv) a refractile cell membrane; (v) rotatory motility; (vi) periodic colonial clustering; and (vii) exists in an extracellular environment; and
- b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin, and metronidazole.

19. The culture of claim 1, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of other organs.

20. The culture of claim 1, wherein said disease is nongonococcal urethritis.

21. The culture of claim 1, wherein said organism proliferates in Diamond's media.

35. A single-celled organism having accession number ATCC PTA-2129.

36. The method of claim 9, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of an organ.

37. The method of claim 9, wherein said organism proliferates in Diamond's media.